

REMARKS

Claims 1-3 and 5-12 were examined. No claims are amended or deleted. Applicants submit additional claims 21-24, and submit that no new matter is added therein as additional claim 21 is supported at least at paragraphs [0051], [0054] and [0055]; additional claim 22 is supported at least at paragraphs [0016], [0051]-[0053], and FIGs. 8-9; additional claim 23 is supported at least at paragraphs [0051]-[0054] and FIG. 9 of the application, and additional claim 24 is supported at least at paragraphs [0030], [0041] and FIG. 3 of the application. Hence, Applicants respectfully request reconsideration of claims 1-3 and 5-12; and consideration of additional claims 21-24.

The Patent Office rejects claims 1-3, 6 and 8 under 35 U.S.C. §102(b) and claims 5, 7, 9 and 10-12 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendment and the following remarks.

A. 35 U.S.C. §102(b): Rejection of Claims 1-3, 6 & 8

The Patent Office rejects claims 1-3, 6 and 8 under 35 U.S.C. §102(b) and (e) as anticipated by U.S. Patent No. 6,162,202 by Sicurelli (Sicurelli), US Patent No. 4,411,657 by Galindo (Galindo), and US Patent No 6,283,951 by Flaherty (Flaherty).

Claims 1-3, 6 and 8 describe a system for detecting tissue contact and penetration depth comprising a needle with a first opening to a lumen of the needle and a second opening to the same lumen of the needle, the needle having the lumen extending between the first opening and the second opening, and the second opening including at least one aperture in the needle to the lumen located at a predetermined distance from the first opening. The system also includes a fluid measurement assembly coupled with a portion of the needle to measure pressure of a fluid dispensed in the needle, including a third pressure that is a pressure change when the needle penetrates tissue and an aperture of a second opening in the needle becomes occluded.

Claims 1-3, 6 and 8 are not anticipated by Sicurelli for at least the reason that Sicurelli does not disclose a pressure measurement assembly configured to measure a third pressure that is a second pressure change when the needle penetrates tissue and the aperture of a second opening located a predetermined distance from the first opening becomes occluded, as required

by claim 1. Sicurelli describes a flexible irrigation syringe tip made of a bendable material such as silicone or propylene to flush a canal such as a tooth canal (see Abstract and column 2, lines 42-67). To this end, the flexible syringe needle may communicating with pressure sensor 550 for controlling the flow pressure of the fluid discharged from the flexible syringe needle during flushing of the canal to safely avoid excess pressure (see column 5, lines 39-51 and 59-67). Sicurelli teaches flushing using openings in the side but not in the tip of the flexible syringe (see FIG. 4). Consequently, Sicurelli does not teach or enable the aperture of a second opening becoming occluded, or measuring a third pressure that is a second pressure change when the needle penetrates tissue and the aperture becomes occluded, as required by claim 1.

Also, claim 1-3, 6 and 8 are not anticipated by Galindo for at least the reason that Galindo does not disclose a pressure measurement assembly configured to measure a third pressure that is a second pressure change when the needle penetrates tissue and the aperture of a second opening located a predetermined distance from the first opening becomes occluded, as required in claim 1. Galindo teaches a hypodermic needle having openings in the perimeter of the needle and having a pinpoint tip without a tip opening, so that the tip can separate nerve fascicles without cutting them (see abstract and Figs. 1-6). Galindo describes fluid pressures of injection when the tip is located inside the muscle, the perineural space and the nerve (see column 2, lines 43-50 and FIG. 8). However, Galindo doesn't teach a distinction between pressure or pressure changes as the openings of the needle become occluded. Hence, Galindo does not teach or enable the aperture of a second opening becoming occluded; or measuring a third pressure that is a second pressure change when the needle penetrates tissue and the aperture become occluded, as required by claim 1.

Next, claims 1-3, 6 and 8 are not anticipated by Flaherty for at least the reason that Flaherty does not teach or enable a pressure measurement assembly configured to measure a third pressure that is a second pressure change when the needle penetrates tissue and the aperture of a second opening located a predetermined distance from the first opening becomes occluded. Flaherty teaches a transvascular system for delivering drug to tissue of a blood vessel using needle: (a) 64 having openings 75 when distal tip 64 of the needle has closed tip 73, or (b) having a single opening 74 in distal tip 64 of the needle (see Abstract; column 10, lines 59-67; and FIG. 5C). In addition, the system of Flaherty may include a pressure sensor provided on needle assembly 62 and/or the drug delivery element to continuously monitor pressure at or near

the delivery site; and/or a flow measurement sensor, allowing the amount of drug being delivered to the selected tissue region to be precisely measured (see paragraph [0017] lines 42-52). However, Flaherty does not describe measuring pressure or flow when an aperture of a second opening in the needle becomes occluded. Consequently, Flaherty does not teach or enable the aperture of a second opening becoming occluded, or measuring a third pressure that is a second pressure change when the needle penetrates tissue and the aperture become occluded, as required by claim 1.

In addition, by having a first opening to a lumen and a second opening to the lumen of the needle, where the second opening includes at least one aperture to the lumen located at a predetermined distance from the first opening, embodiment described in the specification, for example, without limitation thereto, provide numerous unexpected benefits such as: (1) allowing it to be detected when the needle contacts a cavity or vessel wall; and (2) allowing it to be detected when the needed has been inserted a predetermined depth into the cavity or vessel wall, such as where the predetermined depth is the distance between the first hole and the second hole (see at least paragraphs [0004]-[0006], [0030]-[0032] and [0035] of the Application; and Figures 1-3B). However, none of the references teach or enable such benefits.

Hence, Applicant respectfully requests that the Patent Office withdraw the rejection of claims 1-3, 6 and 8 under 35 U.S.C. §102(b).

B. 35 U.S.C. §103(a): Rejection of Claims 5, 7, 9 & 10

The Patent Office rejects claims 5, 7, 9 and 10 under 35 U.S.C. §103(a) as obvious over Sicurelli or Galindo or Flaherty in view of Sicurelli or Galindo or Flaherty. Claims 5, 7, 9 and 10 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated above, claims 5, 7, 9 and 10 are not obvious over Sicurelli or Galindo or Flaherty in view of Sicurelli or Galindo or Flaherty. An argument analogous to the one above for claim 1 applies to show that none of these references teach the above noted limitations of claim 1. Consequently, the combination of these references also does not teach the above noted limitations of claim 1.

In addition, Applicant traverses that given the cited references, the distance of the aperture from the end of the needle would have been an obvious matter of design choice for at

least the reason that Applicant has pointed out unexpected benefits above that provide example advantages and purposes to solve stated problems that are not addressed by simply controlling the amount of flow, as taught by the references. Hence, Applicant respectfully requests that the Patent Office come up with a reference in support of this position in accordance with MPEP § 2144.03. Thus, Applicant respectfully requests that the Patent Office withdraw the rejection to claims 5, 7, 9 and 10 under 35 U.S.C. §103(a).

C. 35 U.S.C. §103(a): Rejection of Claims 11 & 12

The Patent Office rejects claims 11 and 12 under 35 U.S.C. §103(a) as obvious over Sicurelli or Galindo or Flaherty in view of Sicurelli or Galindo or Flaherty in view of U.S. Patent No. 5,662,107 of Sakariassen (Sakariassen). Sakariassen is cited for disclosing a computer processor coupled to a fluid pressure assembly, but does not teach or enable the above note limitations of claim 1.

Claims 11 and 12 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reason stated above for claim 1, claims 11 and 12 are not obvious over the cited references. Applicant respectfully requests that the Patent Office withdraw the rejection to claims 11 and 12 under 35 U.S.C. §103(a).

D. Additional Claims 21-24

Applicants submit additional claims 21-24 are patentable over the cited references for at least the reasons described above in support of their base claim, as well as the additional limitations of claims 21-24.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

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Angelo J. Gaz Reg. No. 45,907

1279 Oakmead Parkway
Sunnyvale, California 94085-4040
Telephone (310) 207-3800
Facsimile (408) 720-8383

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Jessica Huester 12/11/08
Jessica Huester Date